K011287

MAY 2 5 2001

# Appendix 6
# 510(k) Summary of Safety and Effectiveness

A. GENERAL INFORMATION

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|---|---|
| **Submitter's Name:** | Radius Medical Technologies, Inc. |
| **Address:** | 63 Great Road<br>Maynard, MA 01754 |
| **Contact Person:** | Maureen A. Finlayson |
| **Device Generic Name:** | PTCA Guidewire |
| **Device Trade Name:** | Radius Cougar Wire |
| **Classification Name:** | Wire, Guide, Cardiovascular (74DQX) |

B. INDICATIONS

**The Radius Cougar Wire** is intended to facilitate the placement of balloon dilitation catheters during PTCA and/or PTA. The **Radius Cougar Wires** are compatible with all currently approved and marketed PTCA balloon catheters which are labeled for use with an .014 guidewire.

C. DESCRIPTIVE CHARACTERISTICS

The **Radius Cougar Wire** is constructed from a composite stainless steel and Nitinol core to which a coil is attached to the tapered distal section. The proximal section of the wire is coated with PTFE, and the distal coil portion of the wire is hydrophilic coated. The device is packaged in a protective hoop sealed into a Tyvek/mylar pouch, and is sterilized using ETO gas.

D. COMPARATIVE INFORMATION

The **Radius Cougar Wire** is substantially equivalent to the currently marketed **Radius PTCA Guidewire** (K970466).

E. PERFORMANCE TESTING

The following in vitro performance tests were performed on the **Radius Cougar Wire**:

1. Tensile Strength
2. Torque Strength
3. Torqueability
4. Tip Flexibility
5. Coating Adherence/Integrity

CONCLUSION:

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed **Radius Cougar Wire** meets the minimum requirements that are considered adequate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2001

Ms. Maureen A. Finlayson
Radius Medical Technologies, Inc.
63 Great Road
Maynard, MA 01754

Re: K011287
Radius Cougar Wire
Regulation Number: 870.1330
Regulatory Class: II (two)
Product Code: DQX
Dated: April 20, 2001
Received: April 27, 2001

Dear Ms. Finlayson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Radius Cougar Wire

Indications For Use:

Radius Cougar Wire is intended for placement of balloon dilatation catheters during PTCA and/or PTA.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001287